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Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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July 26, 2016

The Honorable Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Acting Administrator Slavitt:

We are conducting oversight of Theranos' failure to comply with federal regulatory standards governing clinical laboratory testing, and the resulting impact on patients nationwide. Such failures led Theranos to recently void two years of test results from its Edison blood-testing device, affecting thousands of patients who may have received inaccurate blood test results and therefore incorrect medical care.[1] Given Theranos' disregard for patient safety and its failure to immediately address concerns by federal regulators, we write to request more information about how regulators are working with Theranos to address these failures. We also request information to better understand the agency's oversight of efforts by Theranos to correct flawed test results sent to medical professionals and patients, and address any harm that may have resulted to patients who received erroneous test results.

On January 25, 2016, the Centers for Medicare and Medicaid Services (CMS), the federal agency charged with clinical laboratory oversight and administration of the Clinical Laboratory Improvement Amendments (CLIA), issued a letter to Theranos citing a number of serious compliance failures discovered at its Newark, California facility pursuant to a November 2015 CMS inspection. Theranos was cited for violating five condition-level CLIA requirements and a number of other standard-level requirements. CMS wrote that some of these compliance violations, "pose immediate jeopardy to patient health and safety."[2]

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[1] *Theranos Voids Two Years of Edison Blood-Test Results*, The Wall Street Journal (May 18, 2016).

[2] Letter from the Centers for Medicare & Medicaid Services, Western Division of Survey and Certification, to Sunil Dhawan, Director, Theranos, Inc. (Jan. 25, 2016).

CMS mandated that Theranos submit information to the agency demonstrating that it had remedied all cited CLIA violations within 10 days of receiving the January 25 letter. Despite providing an extension to submit this information, CMS found that Theranos' submission did not contain a credible allegation of compliance or acceptable evidence that Theranos had corrected the deficiencies cited in the January 25, 2016 letter. CMS subsequently issued a letter to Theranos on March 18, 2016, to put the company on notice that CMS was considering imposing sanctions for Theranos' continued disregard for federal law.[3]

According to news reports, the 121-page inspection report issued by CMS in connection with its January 25, 2016 letter documented serious concerns regarding the accuracy of the tests Theranos marketed in the United States. It appears that both Theranos' proprietary Edison blood-testing devices, as well as tests run by Theranos laboratories using conventional equipment, may have produced inaccurate results.[4] In a particularly troubling finding, news reports indicate that inspectors found that 81 of 81 final patient results reported to patients on the blood thinner Warfarin were not accurate. Too much Warfarin can lead to internal bleeding and too little can leave a patient with an increased risk of stroke.[5] According to news reports, the inspection report also contained what appeared to be comparisons between results from Theranos' proprietary technology and the same samples run on conventional equipment. The comparisons showed that test results differed by 21 percent to 130 percent, although results should have been within 20 percent of one another.[6]

A recent independent assessment conducted by the Icahn School of Medicine at Mount Sinai also raised significant concerns regarding the accuracy of Theranos' tests. The study looked at 22 common clinical laboratory tests and compared the uncertainty and accuracy of results between the Theranos finger-prick blood draw method and two nationwide clinical testing service providers that utilize the traditional venipuncture blood draws (Quest and LabCorp). The study found that Theranos tests yielded results outside their normal range 1.6 times more frequently than results from Quest and LabCorp.[7]

A particularly troubling example highlighted in the study demonstrated that Theranos' results for total cholesterol were lower by an average of 9.3 percent than those produced by

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[3] Letter from the Centers for Medicare & Medicaid Services, Western Division of Survey and Certification, to Elizabeth Holmes, Owner, Theranos, Inc. (Mar. 18, 2016) (online.wsj.com/public/resources/documents/cms20160412.pdf).

[4] *Theranos Devices Often Failed Accuracy Requirements*, The Wall Street Journal (Mar. 31, 2016) (www.wsj.com/articles/theranos-devices-often-failed-accuracy-requirements-1459465578).

[5] *Report Shows Theranos Testing Plagued by Problems*, New York Times (Mar. 31, 2016).

[6] *Id.*

[7] Brian A. Kidd, et al, *Evaluation of direct-to-consumer low-volume lab tests in healthy adults*, Journal of Clinical Investigation (Mar. 28, 2016) (www.jci.org/articles/view/86318/).

Quest and LabCorp.[8] Doctors often use cholesterol data from blood tests to determine whether to prescribe statins, a class of drugs indicated to lower cholesterol levels. The Mount Sinai researchers found the discrepancy in cholesterol results between Theranos and other labs studied was large enough to cause medical professionals to "either inappropriately initiate or fail to appropriately initiate statin therapy" in some patients.[9]

Recently, in response to regulatory action taken by CMS, Theranos announced that the company has voided two years of results from its Edison blood-testing devices, and has issued tens of thousands of corrected blood-test reports to doctors and patients.[10] According to the company's recent announcement, these tests represent less than one percent of all blood test results provided by Theranos.[11] However, this appears to contradict Theranos' own statements about the percentage of patients receiving tests using Theranos' proprietary technology. In October 2015, the company stated that "by the fourth quarter of 2014, 57 percent of guests got lab tests run on finger-stick samples. This transition was by choice—not by necessity. In December of 2014, more than 80 tests on Theranos' online test menu were offered via finger-stick and performed using proprietary technologies."[12] Additionally, a Theranos spokesperson recently stated that no patients have suffered harm due to the inaccurate tests, citing an internal analysis conducted by the company; the company has not provided details of the analysis publicly.[13]

It is unclear whether the corrected blood-test reports Theranos has issued thus far capture the universe of inaccurate blood test results that the company has provided patients. Given that the corrected blood-test reports appear to be focused on test results from the proprietary Edison blood-testing devices, it is unclear whether Theranos has addressed the universe of inaccurate test results arising from testing using conventional devices.[14]

Given our ongoing concerns about Theranos' compliance with federal statutes and regulations and the quality and accuracy of Theranos' testing, we are requesting that you provide a briefing to Committee staff on the following issues:

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[8] *Id.*

[9] *Id.*

[10] *Theranos Voids Two Years of Edison Blood-Test Results*, The Wall Street Journal (May 18, 2016).

[11] *Theranos Says Only 1% of Results Affected; Some Doubt Tests*, Associated Press (June 3, 2016); *Theranos Has Thrown Out Two Years of Blood-Test Results*, Fortune (May 19, 2016).

[12] *Theranos Facts*, Theranos, Inc. (Oct. 22, 2015) (www.theranos.com/news/posts/custom/theranos-facts) (accessed June 7, 2016).

[13] *Theranos Issues Thousands of Blood-Test Corrections*, CNN Money (May 19, 2016).

[14] *Theranos Voids Two Years of Edison Blood-Test Results*, The Wall Street Journal (May 18, 2016).

1) Please provide an overview of the CLIA violations identified in the agency's November 2015 inspection of Theranos' Newark, California laboratory, and how the agency determined that the "deficient practices of the laboratory pose immediate jeopardy to patient health and safety."

    a. Has the agency conducted an inspection of Theranos' Palo Alto, California laboratory or Theranos' laboratories located in Arizona? If so, please provide additional information regarding the inspection history of these facilities, as well as the type of inspections that have been conducted previously. Further, please provide information regarding the future inspection schedule for these facilities.

2) Please provide an overview of Theranos' response to the agency's January 25, 2016 letter, and the agency's determination that Theranos' response did not provide "a credible allegation of compliance and acceptable evidence of correction for the cited deficiencies."

3) Please provide an update on Theranos' efforts to work with the agency to come into compliance with federal law, including the company's ongoing efforts to address the deficiencies and compliance issues identified in CMS's January 25, 2016 letter and accompanying inspection report.

    a. How has Theranos been working with the agency to change its internal policies to prevent future compliance issues associated with its laboratories?

4) Please describe the agency's oversight of efforts Theranos is taking to correct flawed test results sent to medical professionals and patients, and address any harm that may have resulted to patients who received erroneous test results.

    a. What is CMS's role in this regard? Is CMS confident that Theranos has issued corrected test results to the universe of patients who received erroneous test results, whether these tests were run on the proprietary Edison blood-testing devices, or on conventional machines? Please explain.

    b. Theranos has publicly represented that no patients have been harmed due to inaccurate test results. Has the agency reviewed Theranos' analyses and reached a similar conclusion? Please explain.

5) On July 7, 2016, Theranos announced the company received notice from CMS regarding sanctions the agency would be imposing. Those sanctions include: revocation of the laboratory's CLIA certificate, which includes a prohibition on the owners and operators of the lab from owning, operating, or directing a lab for at least two years; a limitation of the laboratory's CLIA certificate for the specialty of hematology; an undisclosed civil monetary penalty; a directed portion of a plan of correction; suspension of the laboratory's approval to receive Medicare and Medicaid payments for any services performed for the specialty of hematology; and, cancellation of the laboratory's approval

to receive Medicare and Medicaid payments for all laboratory services. Please provide additional information regarding the agency's decision to issue these sanctions, as well as further information about the sanctions themselves and the effective date of the imposed sanctions.

We would appreciate your response to this request as soon as possible, but no later than August 10, 2016. If you have any questions regarding this request, please contact Kimberlee Trzeciak of the Democratic staff at 202-225-3641.

Sincerely,

Frank Pallone, Jr.
Ranking Member

Gene Green
Ranking Member
Subcommittee on Health

Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations